ILLINOIS HEALTH INFORMATION EXCHANGE

Resolution Number 2014-08

Resolution Adopting the Patient Consent Preferences and Data Security Work Group "2014 Annual Review"

WHEREAS, the Data Security and Privacy Committee of the Illinois Health Information Exchange Authority Board has submitted for the Board's consideration its recommendation for adoption of the Patient Consent Preferences and Data Security Work Group's "2014 Annual Review" ("Review"), which has been provided to the Board and is attached hereto as Exhibit A and incorporated herein; and

WHEREAS, the Board has reviewed, and endorses the Review and the Patient Consent Preferences and Data Security Work Group's recommendation contained therein.

BE IT RESOLVED BY THE ILLINOIS HEALTH INFORMATION EXCHANGE AUTHORITY, AS FOLLOWS:

Section 1. Authority. This resolution is adopted pursuant to Section 15(e) of the Illinois Health Information Exchange and Technology Act, 20 Illinois Compiled Statutes 3860/1 et seq.

Section 2. Adoption of the Patient Consent Preferences and Data Security Work Group's "2014 Annual Review."

RESOLVED, the Board hereby adopts the Patient Consent Preferences and Data Security Work Group's "2014 Annual Review"; and

RESOLVED, the Board hereby directs the Patient Consent Preferences and Data Security Work Group to continue its review of available technology and provide another report to the Board at its July, 2015 meeting.

Section 3. Enactment. This resolution shall take effect immediately. If any section, paragraph or provision of this resolution shall be held to be invalid or unenforceable for any reason, the invalidity or unenforceability of such section, paragraph or provision shall not affect any of the remaining provisions of this resolution.

Adopted this 23rd day of July, 2014 by a majority vote of the appointed members as follows:

Ayes:
Nays:
Abstain:
Absent:

_____

Kerri L. McBride
Secretary

ILLINOIS HEALTH INFORMATION EXCHANGE

Exhibit A

PATIENT CONSENT PREFERENCES & DATA SECURITY WORK GROUP

2014 ANNUAL REVIEW

Background

On August 16, 2013 Governor Quinn signed House Bill 1017 into law (PA 098-0378).[1] Public Act 098-0378 amends the Illinois Mental Health and Developmental Disabilities Confidentiality Act ("MHDDCA"). It delegates to the Illinois Health Information Exchange Authority (the "Authority") the responsibility to annually review the feasibility, availability, cost, reliability, and interoperability of adopting new technologies that allow for segmentation within a medical record. Specifically, the MHDDCA, as amended, directs the Authority to "give annual consideration to enable a [patient] to expressly decline the further disclosure by [a health information exchange] to third parties of selected portions of the [patient's] record while permitting disclosure of the [patient's] remaining patient health information".[2]

On June 26, 2013 the ILHIE Authority convened the Illinois Patient Consent Management Workshop ("Workshop"). The Workshop began the process by which the Authority considers the development of the privacy, security, and consent policies to govern the exchange of patient data utilizing health information exchange ("HIE") in Illinois for which the Authority is responsible pursuant to the MHDDCA amendment.

The Workshop invited Illinois health care stakeholders to participate in three privacy and security work groups; the Patient Consent Preferences and Data Security Work Group (the "Work Group") is one of those groups. The purpose of the Work Group is to develop recommendations for presentation to the Authority Board regarding its statutory requirement for an annual review of the technology to support data segmentation and prioritize such technology solutions according to population impact and technical feasibility.

Fiscal Year 2014 Review Summary

At its inaugural meeting, the Work Group adopted a Project Charter (Attachment 1) to guide the Work Group's activities for the Fiscal Year 2014 review ("Review Year"). The Project Charter outlined the following process to identify and evaluate possible data segmentation solutions:

1. Gather the concerns of Illinois patients and patient advocates and identify specific data security concerns arising from various patient consent preference scenarios;
2. Develop "personas" (use cases) to represent those concerns;

[1] PA 098-0378 available at: http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=098-0378&GA=98.
[2] 740 ILCS 110/9.6

3. Host educational technical presentations to learn about existing and developing technologies;
4. Evaluate potential solutions for relevance, feasibility, availability, cost, reliability, and interoperability; and
5. Make recommendation(s) to the Authority Board pursuant to the Authority's MHDDCA's annual technology review requirement.

The Work Group activities closely paralleled the outlined process, with a principal focus on hosting presentations on several existing and developing technologies related to data segmentation. The Work Group reviewed four available solutions and concepts, each of which is summarized below. However, while a variety of segmentation technologies are in development and testing, no technology reviewed by the Work Group was commercially viable at the time of the Work Group's deliberations and analysis.

The Work Group began development of a framework for evaluating potential technology solutions. The Work Group intends to utilize the framework when the market offers sufficiently-mature potential solutions for evaluation. It is anticipated that sufficiently-mature solutions will be available within the next few years. The proposed framework consists of two components: first, a matrix of requirements and factors by which to assess a technology, and second, application of the solution to personas (use cases). The Work Group began the process of developing the evaluation criteria matrix (Attachment 2) during this Review Year. The matrix will require further explication by the Work Group over the next year. The Work Group also began developing the personas that will be used to understand the impact of real-world privacy issues on the technical challenge of exchanging protected health information, including health information of a sensitive nature. The Work Group members believe an expanded matrix and the personas together will enable a comprehensive evaluation of potential future solutions.

ILHIE Authority Standards

State law designates Illinois' statewide consent policy for patients participating in health information exchange ("HIE") as opt-out. Participants (providers) in the ILHIE are responsible for segregating out any data that a patient does not wish to share. If a participant is not capable of segregating data, patients that do not wish to share portions of their health information must opt-out with that participant to prevent the disclosure of health information to other HIE participants.

Upon joining the ILHIE, participants, unless otherwise specified, upload their patient demographic information to the ILHIE Master Patient Index and make patients' records available for query for a permitted purpose by an authorized ILHIE user. As the result of the State's opt-out policy, a patient's electronic medical record ("EMR") is available for disclosure upon a query. However, patients have the right to opt-out of HIE participation on a participant-by-participant basis. Therefore, if a patient is uncomfortable allowing Participant A to share information

through the ILHIE, the patient can opt-out with Participant A while continuing to participate with and making available the information held by Participant B.

There are a variety of ways that an EMR can interact with the ILHIE to implement a patient opt-out choice. The Authority's preferred approach is to use the Integrating the Health Enterprise ("IHE") technical standard, a XACML consent document, but the Authority can provide other alternatives including admission/discharge/transfer ("ADT") feeds for those EMRs that cannot provide the XACML document.

During the first Review Year, the Work Group reviewed three different approaches to data segmentation: Consent2Share, Data Segmentation for Privacy ("DS4P") and Strategic Healthcare IT Advanced Research Projects on Security ("SHARPS") Decision Support for Data Segmentation ("DS2"). The Work Group and also discussed a fourth segmentation approach based on using clinical relationships between patients and providers to control disclosure (the "Clinical Relationships Model"). However, the Work Group is not aware of a current specific technology that uses the Clinical Relationships Model. Demonstrations of Consent2Share, DS4P and the SHARPS DS2 approaches and system capabilities were provided to the Work Group.

Work Group Technology Review

The three technologies reviewed by the Work Group are primarily for use with the CCD or the C32; the technologies do not take into account the other documents in the CCDA suite, ADT feeds, or HL7. These technologies apply only to structured data, ignoring free text. The technologies reviewed by the Work Group are not currently commercially available for purchase. Following are the Work Group's conclusions related to the four technologies and concepts it reviewed in this Review Year.

Consent2Share

Consent2Share is a sophisticated model created by the federal Substance Abuse and Mental Health Service Administration ("SAMHSA"). Consent2Share has the following features:

- It allows patients to determine which segments of a CCD can be shared between providers in an electronic exchange.
- It integrates with a patient portal giving the patient direct control over the segmentation of his or her data.
- It has been successfully integrated with the Veterans Administration's Vista system.
- Its functionality can be integrated with the Office of the National Coordinator for Health Information Technology's ("ONC") Direct secure messaging.

Consent2Share is not commercially available; and the Work Group found it complex to operate and configure. The Consent2Share infrastructure requires both the HIE participant and the HIE to implement a Consent2Share installation. In addition, the Authority has not yet deployed a patient portal which is a necessary precondition to the use of this approach. As of this report, the Work Group is not aware of Consent2Share being used in a production environment. As a result, the Work Group does not support an attempt to deploy the solution in the ILHIE system at this time.

Data Segmentation for Privacy

Data Segmentation for Privacy is the Veterans Administration approach to data segmentation. The DS4P scheme metadata has three components:

- Confidentiality Codes
- Purpose of Use Codes
- Obligation Codes
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These metadata codes (or tags) are applied to different portions of a CCD based on the different levels of the relative-confidentiality of patient data. Segmentation works through a 'high watermark' approach. Under this approach, the highest level of confidentiality and obligation that is established for the transaction is carried through to the content. Application of the codes can result in restricted visibility to the data.

DS4P has been widely vetted by cross-industry groups, including the Standards and Interoperability ("S&I") Framework, IHE, HL7 International, Institute of Medicine ("IOM"), National Institute of Occupational Safety and Health ("NIODH"), Centers for Disease Control and Prevention ("CDC"), and six S&I DS4P Pilots. These collaborative efforts addressed many of the legal, ethical and technical issues related to data flow that were raised by stakeholders Additional review and refinement of DS4P specifications and legal and technical issues are under consideration. This technology warrants additional review by this Work Group as it matures.

Strategic Healthcare IT Advanced Research Projects on Security Decision Support for Data Segmentation

SHARPS DS2 is a technical architecture and software prototype that demonstrates how OpenCDS, an open source Clinical Decision Support ("CDS") framework, can be used to identify and redact selected conditions from clinical summary documents in an HIE environment. DS2 features are as follows:

- Identify if a clinical document has a particular type of sensitive data in it
- Redact portions of the clinical document until corresponding predicate is satisfied
- Check care plan against non-redacted clinical document

ILHIE/SHARPS Segmentation Project

The ILHIE/SHARPS segmentation project was a joint project between the Authority and the University of Illinois SHARPS Project. The team used the DS2 technical architecture and prototype to built a segmentation process that could "wrap itself around" a commercial HIE to provide segmentation services without having to reconfigure the base HIE software. This project was not intended to create a commercial product, but rather to uncover issues involved in segmentation as well as novel approaches to implementing a solution.

Clinical Relationships Model

The Work Group did not identify a specific technology that uses the Clinical Relationships Model; however, the Work Group is discussing this approach to solicit feedback, particularly from the provider community. If there is significant interest, there may be vendors willing to provide technology to implement technology using the Clinical Relationships Model.

While segmentation limits the data a provider can see, it does not to guarantee that whoever accesses a patient's data is authorized to access that data for a permissible purpose. The Clinical Relationships Model focuses not on the content of the data but rather on who should have authority to access to the data. Under the model, only individuals with a clinical (treatment) relationship with the patient would be authorized to access the patient's data. The audit trail is one vehicle that can be used to deduce whether there is a treatment relationship between a provider and a patient. The SHARPS Project has already conducted research aimed at developing this idea. The other component of the Clinical Relationships Model is a patient portal that allows the patient to decide who may access his or her data beyond individuals with a discernable clinical relationship with the patient. Patients may also use the portal to produce an on demand report to determine who has accessed his or her data, at what time and for what reason.

The Work Group is hopeful that this approach will eventually move from research to commercialization. The Clinical Relationships Model is not necessarily an alternative to segmentation; it can potentially be used in conjunction with segmentation. The Work Group will continue to monitor developments using the Clinical Relationships Model approach.

Patient Privacy Concerns and Personas

Regardless of the technological security safeguards implemented, a technological solution must be able to segment health information that is of a sensitive nature, protected by law, or both.

In beginning to document individual patient privacy concerns with regard to sensitive health information which may be protected by federal or State law, the Work Group principally categorized concerns relating to the following:

- Reproductive health
- Minors
- HIV testing and results
- Substance abuse
- Genetic testing data

Regardless of pending or future law changes that remove barriers to the sharing of patient health information for health information exchange, entrenched perceptions or cultural attitudes towards certain types of health data will be more difficult to change. To change those perceptions and concerns, HIE participants may be required to commit more time and resources to educating the patient population and creating or implementing new procedures and patient consent or authorization collection.

The Work Group plans to develop a set of personas to reflect patient privacy concerns in the second review year

Meaningful Use and Impact on HIE Initiatives

Currently, data segmentation is neither a Meaningful Use requirement nor an EHR certification requirement as defined by the Centers for Medicare and Medicaid Services or the ONC. However, as robust health information exchange facilitates care coordination initiatives, concerns regarding barriers to the ability to share patient information have been raised by HIEs and care coordination entities, among others. In particular, several of the technology solutions examined by the Work Group are a direct result of initiatives under the direction of federal agencies.

The Work Group acknowledges regulatory guidance provided by both the ONC and SAMHSA in regard to the exchange of certain specially protected health information. Of particular note, in its most recent recommendations to the ONC Health IT Policy Committee, the ONC Privacy and Security Tiger Team recognized the relative immaturity of the EMR market to support data segmentation.[3] The recommendations

[3] Privacy & Security Tiger Team: Input on C/A Workgroup Recommendations for Behavioral Health and CEHRT. Presentation and ecording available at: http://www.healthit.gov/FACAS/calendar/2014/06/10/hit-policy-committee-virtual.

from the Tiger Team to the Health IT Policy Committee included a request for additional federal regulatory clarifications, advocate for additional pilots to test operational and work workflow issues surrounding data segmentation, and recommended the Health IT Policy Committee signal the need for EMR vendor solutions to support data segmentation by advancing data segmentation capabilities within the framework of Meaningful Use.

Work Group Recommendations

For the Review Year ending on June 30, 2014, the Work Group makes no recommendation to the Authority Board of any single specific technology solution or data segmentation mechanism. The potential technical segmentation solutions reviewed by the Work Group during the Review Years are insufficiently mature to support a recommendation. . Additionally, the potential solutions reviewed by the Work Group are not commercially available. In the upcoming review years, the Work Group recommends that the Work Group: (1) review and update the Charter, and (2) continue to develop and refine the technology solution evaluation criteria matrix and the personas to enable a full evaluation of possible solutions as the segmentation market matures.